

Materials Reviewed

- 1. Amy G. Egan, et al., *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, N. Eng. J. Med. 794, 795 (Feb. 27, 2014).
- 2. Citizen's Petition: Docket No. FDA-2012-P-0404 (April 19, 2012).
- 3. FDA's response to the Citizen's Petition: Docket No. FDA-2012-P-0404 (March 25, 2014).
- 4. FDA Drug Safety Communication: FDA investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes (March 14, 2013).
- 5. Labeling for incretin-based therapies, including Byetta (exenatide), Bydureon (exenatide extended release), Victoza (liraglutide), Januvia (sitagliptin), Janumet (sitagliptin and metformin), Onglyza (saxagliptin), Tradjenta (linagliptin), Nesina (alogliptin), Trulicity (dulaglutide), and Tanzeum (albiglutide).
- 6. National Institute of Diabetes and Digestive and Kidney Diseases Workshop on Pancreatitis, Diabetes, Pancreatic Cancer, June 12-13, 2013 (abstracts of presentations by FDA's Dr. Solomon Iyasu and Dr. Timothy Hummer).
- 7. FDA Staff Manual Guide (SMG 2126.3: Review of FDA-Related Articles and Speeches).
- 8. Relevant FDA regulations, guidance documents, standard operating procedures, and statements in the Federal Register.